UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

PAMELA STELLA, individually and on behalf of all others similarly situated, Plaintiff, v. LVMH PERFUMES AND COSMETICS USA, INC., a New York Corporation, Defendant.	No. 07-CV-6509 Hon. Elaine E. Bucklo Magistrate Judge Arlander Keys

DEFENDANT LVMH PERFUMES AND COSMETICS USA, INC.'S
MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY

In this seven-count putative class action, plaintiff Pamela Stella ("plaintiff") has alleged that Defendant LVMH Perfumes and Cosmetics USA, Inc. ("LVMH")[1] has violated state and federal law by manufacturing, marketing, and/or selling lipsticks that supposedly contain dangerous undisclosed levels of lead. Fundamental to each of plaintiff's claims is the highly questionable proposition that any amount of lead whatsoever (even a trace amount of lead) is *ipso facto* dangerous and that LVMH, therefore, had an affirmative obligation to disclose the presence of even trace amounts of lead in its lipstick to consumers.

Whatever the merit of these charges, however, it is certain that plaintiff's claims raise at least two interrelated threshold questions that are beyond the conventional experience of the courts: (1) whether trace amounts of lead in lipstick give rise to legitimate health concerns; and (2) whether trace amounts of lead in lipstick trigger any disclosure obligations under applicable

[1] Plaintiff names LVMH Perfumes and Cosmetics USA, Inc. as the defendant in this lawsuit. No such entity exists. The proper name of the entity that plaintiff presumably intends to sue is LVMH Perfumes and Cosmetics, Inc. (hereinafter "LVMH"). LVMH reserves the right to later argue that it is not, in any event, a proper defendant in this lawsuit.

federal law. Rather than being amenable to conventional adjudicative methods, both questions implicate the specialized expertise and regulatory prerogative of the U.S. Food & Drug Administration ("FDA"), the federal agency charged by Congress with regulating cosmetic products in the U.S. Notably, not only has the FDA promulgated lead-content and labeling standards in a variety of contexts,[2] but it has also evaluated prior claims relating specifically to the presence of lead in lipstick and found no harm.[3] Moreover, the FDA has recently stated publicly that it is now conducting its own investigation into these issues. Under the doctrine of primary jurisdiction, this Court should stay these proceedings until the FDA completes its work.[4]

The doctrine of primary jurisdiction is a judge-made doctrine concerned with promoting proper relationships between courts and administrative bodies. *See, City of Peoria v. General Electric Cablevision Corp.*, 690 F.2d 116, 120 (7th Cir. 1982). Recognizing that the courts may benefit from the specialized knowledge and expertise of the agencies, and that the interests of judicial economy and substantial fairness may be better served, the doctrine of primary

[2] For example, the FDA has enacted a lead standard (.0005 mg/l) for bottled water, a product consumed in large quantities by millions of American consumers every day. *See* 21 CFR § 165.110(b) [Table 2]. The FDA has also established a *recommended* maximum lead level of 0.1 ppm in candy likely to be consumed frequently by small children. *See* FDA Center for Food Safety and Applied Nutrition Guidance Document, "Lead in Candy Likely to Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," Nov. 2006, *at* http://www.cfsan.fda.gov/~dms/pbguid3.html. (A hardcopy of the FDA "Lead in Candy" Guidance Document is attached as Ex. A). Significantly, this voluntary lead-in-kids'-candy standard is the very same standard the plaintiff suggests by her complaint should be mandatory with respect to lipstick.

[3] *See* FDA Center for Food Safety and Applied Nutrition Press Release: "Lipstick and Lead: Questions and Answers," Dec. 27, 2007, *at* http://www.cfsan.fda.gov.~dms/cos-pb.html (FDA's previous analysis of such claims "did not detect levels of lead that would be considered harmful . . . [and] . . . [t]he levels found did not exceed amounts that would be unavoidable even under conditions of good manufacturing practice given background levels in the environment.") ("FDA Lead in Lipstick Press Release" attached as Ex. B.)

[4] *See* Ex. B, FDA Lead in Lipstick Press Release ("FDA has decided to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market. FDA has obtained commercial samples of the same lipstick brands cited in the recent report [CSC Report]. FDA laboratories have been adapting a previously validated, state-of-the-art method to do the analysis.")

jurisdiction allows the courts to stay, dismiss, or refer cases that "involve[] an issue . . . that Congress wants one of the administrative agencies to have first crack at." *Id.*

Here, Congress has empowered the FDA as *the* administrative body specifically charged with regulating the safety and labeling requirements of cosmetics pursuant to, *inter alia*, the Food Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDC Act"), and the Fair Packaging and Labeling Act, 19 U.S.C. § 1451 *et seq*. ("FPLA"). Several prominent members of Congress have requested that the FDA respond to a recent report regarding lead in lipstick.[5] Further, as noted above, the FDA has already publicly stated that it has initiated its own evaluation of the relevant issues. Under such circumstances, the doctrine of primary jurisdiction is plainly applicable, and this lawsuit should be stayed in its entirety while the FDA addresses the predicate issues regarding lead safety and labeling requirements with respect to lipstick.

BACKROUND

A. The CSC Report and Follow-On Lawsuits.

In October 2007, a private consumer advocacy group, calling itself The Campaign for Safe Cosmetics ("CSC"), issued a report arguing that a significant number of brand-name lipsticks sold in the United States contain dangerous levels of undisclosed lead. (*See*, "A Poison Kiss: The Problem of Lead in Lipstick," The Campaign for Safe Cosmetics (Oct. 2007) ("CSC Report"), at www.safecosmetics.org.) The CSC Report contended that more than half of the thirty-three lipsticks it tested contained miniscule, but still detectable levels of lead (ranging from 0.03 to 0.65 parts per million (ppm)). The CSC Report also asserted (however incongruously) that some of these levels exceeded the 0.1 ppm standard enacted by the FDA for lead in candy.

[5] On November 19, 2007, in an open letter to Dr. Andrew C. von Eschenbach, the Commissioner of the FDA, U.S. Senators John Kerry (D-Mass.), Barbara Boxer (D-Calif.), and Dianne Feinstein (D-Calif.) called upon the FDA to initiate a full investigation into recent claims regarding lead in lipstick.

The alarmist tone of the CSC Report notwithstanding, the presence of trace amounts of lead in lipstick is not news. Lead is a naturally occurring element found in the environment, including in pigments used to color some lipsticks.[6] Notably, these pigments are heavily regulated as "color additives" by the FDA, which has prescribed the allowable lead content.[7] Further, the FDA has been monitoring levels of lead in lipstick since at least the 1990's and has consistently found that trace amounts of lead in lipstick are not harmful.[8] Moreover, the FDA has flatly rejected the CSC's attempted comparison between the FDA's recommended standard for lead in candy (intended for ingestion in significant quantities) and lead levels in lipstick (ingested only inadvertently in tiny quantities).[9] In short, the CSC's conclusion that trace levels of lead detected in certain lipsticks are *per se* dangerous and, thus, cause for alarm is fundamentally flawed.

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[6] It is common knowledge in the cosmetics industry that lead is not an "ingredient" in lipstick. Any trace amount of lead in lipstick is the result of environmental exposure in the manufacturing process (*e.g.*, lead in the air; lead in the water) and/or trace amounts of lead in the raw materials used in the FDA-regulated pigments used to color some lipstick. Federal law recognizes that not everything in a finished product is an "ingredient" subject to disclosure. *See, e.g.*, 21 C.F.R. § 701.3(l)(1), discussed *infra*, pp. 6-7.

[7] The color additives used in cosmetics are subject to a strict approval process under federal law. See FDC Act, 21 U.S.C. §379e; 21 CFR Parts 70 and 80. A summary of the regulatory scheme relating to color additives and cosmetics is posted on the FDA website, *at* http://www.cfsan.fda.gov/~dms/cos-col.html. (A hardcopy of the summary, entitled "Color Additives and Cosmetics," is attached as Ex. C.)

[8] *See*, *supra*, fn. 3.

[9] *See* Ex. A, FDA Press Release (stating that it is "not valid" to compare the FDA-recommended level for lead in candy with lead levels in lipstick). Further, repeated daily use of lipstick containing even 0.65 ppm of lead (the highest level reported in the CSC Report and more than three times the level allegedly contained in the complained-of lipstick in this case) results in a maximum daily ingestion of 0.033 µg/day of lead. *See* http:/eurlex.europa.er/LexUriServ/site/en/oj1998/l_33019981205en00320054.pdf. The FDA-determined Provisional Total Tolerable Intake Level ("PTTIL") for lead in adults is 75 µg/day. By comparison to PTTIL, the maximum level of daily lead exposure from lipstick is infinitesimally small – 0.033 µg/day of lead is a mere 0.044% of the FDA-approved PTTIL for lead in adults. Even compared to FDA's PTTIL for children 6 years of age and below (6 µg/day) and children 7 years of age and above (15 µg/day), the maximum level of exposure from lipstick is truly miniscule – 0.22% of PTTIL and 0.55% of PTTIL, respectively. *See* Health Consultation Exposure Investigation ("HHS Report"), U.S. Dep't of Health & Human Svcs., June 9, 2005 (identifying PTTIL for lead in children and adults), *at* http://www.atsdr.cdc.gov/HAC/PHA/HerculaneumLeadSmelterSiteEI/HerculaneumLeadSmelterFinalEI060905.pdf. (A hardcopy of the excerpted HHS Report is attached as Ex. D.)

Despite its shortcomings, the CSC Report has spawned a number of lawsuits (including the present action) against certain of the cosmetic companies identified in the Report.[10] These cases suffer from myriad legal and factual defects,[11] but even the most basic liability issues on each of the asserted claims assume resolution of certain predicate issues: first, whether the reported levels of lead in lipstick are actually dangerous (as the CSC Report and the follow-along plaintiffs suggest); and, second, whether cosmetics companies have an obligation to disclose the presence of trace amounts of lead in their lipsticks. These issues are squarely and uniquely within the regulatory ambit of the FDA and, thus, are within the FDA's primary jurisdiction.

B. FDA Legal Authority With Respect to Cosmetics

Congress vested the FDA with regulatory authority over the interstate manufacturing, marketing, and distribution of food, drug, and cosmetic products in the United States. The FDA's legal authority over cosmetics is different from certain other products regulated by the agency (including, *e.g.*, drugs, biologics, and medical devices) in that the FDA does not have blanket pre-market approval authority for cosmetic products. Nevertheless, the FDA's authority with respect to cosmetic products is extensive. As set forth below, the FDA regulates cosmetic packaging and labeling.[12] The FDA has pre-market approval authority for all color additives

[10] In addition to the present case, LVMH counsel is aware of three virtually identical "lead in lipstick" lawsuits: *Quinn v. LVMH Perfumes and Cosmetics USA, Inc*., No. 08-C-138 (N.D.Ill.) (filed Jan. 7, 2008) (Grady, J.); *Don's Frye v. L'Oreal SA, France*, No. 08-C-213 (N.D.Ill.) (filed Jan. 9, 2008) (Gettleman, J.); and *Koronthaly v. L'Oreal USA, Inc. et al.*, No. 2:07-CV-5588 (D.N.J.) (filed Nov. 21, 2007).

[11] The factual and legal deficiencies affecting the complaint in this action are beyond the scope of this motion to stay. If this lawsuit is eventually allowed to proceed, LVMH respectfully reserves the right to thereafter assert all available defenses in a proper motion under Fed. R. Civ. P. 12(b) within a reasonable period of time determined by this Court.

[12] FDA regulation of cosmetic labeling is extensive. *See, e.g.,* FDA's "Cosmetic Labeling Manual" (summarizing relevant packaging and labeling requirements), *at* http://vm.cfsan.fda.gov/~dms/cos-lab1.html. (A hardcopy of the FDA Cosmetic Labeling Manual which is attached as Ex. E.)

used in cosmetics.[13] The corresponding FDA listing for each color additive includes limits for trace levels of heavy metal contaminants, including lead. Moreover, the FDC Act generally requires that cosmetics marketed in interstate commerce be safe when used as directed in the labeling or under customary conditions of use.

The FDA's authority with respect to cosmetics derives primarily from two statutes, the FDC Act and the FPLA (the Fair Packaging & Labeling Act). Under the FDC Act and its implementing regulations, the FDA is authorized to take regulatory action against adulterated or misbranded cosmetic products.[14] Indeed, Plaintiff seeks to usurp the FDA's authority by seeking broad injunctive relief to prevent LVMH from distributing, selling and or manufacturing products which she incorrectly alleges violate the FDC Act. Likewise, under the FPLA and its implementing regulations, the FDA requires that "ingredients" contained in regulated products, including cosmetics, be properly disclosed so that consumers can make informed purchasing decisions. Cosmetic products that fail to comply with FPLA labeling requirements are considered misbranded for purposes of the FDC Act and are subject to regulatory action.

As noted *supra* (*see* fn. 14), whether a cosmetic product is adulterated or misbranded depends largely on whether any constituent ingredient renders the product unsafe. FDA regulation in this respect is extensive. For example, the FDC Act's implementing regulations exempt "incidental ingredients" from the labeling requirements otherwise applicable under the

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[13] *See*, *supra*, fn. 7.

[14] Under the FDC Act, a cosmetic product is adulterated if (1) it bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual, or (2) it is, or it bears or contains, a color additive that is unsafe within the meaning of section 721(a) of the Act. A cosmetic product is misbranded under the FDC Act if, among other things, its labeling is false or misleading, it does not include all required information, it is a color additive that does not conform to applicable regulations issues under section 721(a) of the Act, or it otherwise fails to conform to the requirements of the FPLA. *See* FDC Act, 21 U.S.C. §§ 331, 361, 362.

Act. Specifically, 21 C.F.R. § 701.3, which governs ingredient labeling in regulated cosmetics, provides, in relevant part, that:

> The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are: (1) substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.

21 C.F.R. § 701.3(l)(1).

Accordingly, if lead is present in lipstick at an insignificant level and only because it was a constituent of some other ingredient in the lipstick, under 21 C.F.R. § 701.3(l)(1), then it is an "incidental ingredient" that does not have to be disclosed on the product packaging or label. Likewise, 21 C.F.R. § 740.10 only requires a warning or similar disclosure statement on a product if "adequate substantiation of safety has not been obtained." Each of these determinations – *i.e.*, whether the amount of lead in a cosmetic product is truly insignificant, whether the lead serves any technical or functional purpose, and whether adequate substantiation of safety has been obtained – requires a level of complex, technical, scientific inquiry for which the FDA is uniquely suited.

Indeed, to some extent, the FDA has already undertaken this task. First, as noted above, the FDA has investigated prior claims regarding lead in lipstick and determined that the levels of lead were not actionable.[15] In addition, although the FDA does not have pre-market approval authority for finished cosmetic products, it does have pre-market approval authority for the color additives used in cosmetics, each of which must undergo an extensive approval process.[16] As the CSC Report acknowledges, the FDA has established limits on the amount of heavy metals

[15] *See*, *supra*, fn. 3.

[16] *See*, *supra*, fn. 7.

(including lead) allowed in FDA-approved color additives, including those used in lipstick. Those limits are currently set at 10-20 ppm. The FDA has not yet found it necessary or appropriate to set a limit on the amount of colorant that may be used in cosmetics. Notably, however, there is no indication in the CSC Report (and no allegation in the complaint) that the amount of lead in the colorants used in lipsticks exceeds the limits prescribed by the FDA.

Finally, if the FDA has information that a cosmetic product is adulterated or misbranded, it has extensive regulatory options at its disposal. The FDA has broad discretion whether to initiate regulatory action based on the agency's priorities, public health concerns, and available resources. It can enlist the Department of Justice to bring an action in the federal courts to remove adulterated or misbranded products from the market. It can seek a restraining order from a federal district court to enjoin further distribution or shipment of an adulterated or misbranded product. Domestically produced adulterated or misbranded products may also be seized. Imported cosmetics are likewise subject to review by the FDA at the time of inspection, and products that do not comply with U.S. law may be refused admission into the U.S., destroyed, or re-exported. The FDA may also initiate criminal and civil proceedings against violators.

ARGUMENT

Each of plaintiff's claims is predicated on the doubtful proposition that the trace amount of lead allegedly detected in Dior® "Addict Positive Red" lipstick is dangerous and, therefore, that LVMH was obligated to disclose the presence of lead to plaintiff and other members of the putative class. Even apart from the independent proof of the safety of its products that LVMH is prepared to submit in this case, and the propriety of its marketing and labeling practices generally, LVMH submits that the predicate issues regarding the safety of the complained-of lipstick and the extent to which a lead disclosure statement was required under the existing

regulatory scheme are within the primary jurisdiction of the FDA and that this action. Therefore, this action should be stayed pending the FDA's examination of those issues.

The doctrine of primary jurisdiction "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *AT&T Corp. v. Ameritech Corp*., No. 98-C-2993, 1998 U.S. Dist. LEXIS 9175, *3-4 (June 9, 1998) (*citing U.S. v. Western Pacific Railroad Co*., 352 U.S. 59, 64, 77 S. Ct. 161 (1956) (internal quotations omitted) (attached as Ex. F). As the Seventh Circuit stressed in *Hansen v. Norfolk and Western Railway Company*, 689 F.2d 707 (7th Cir. 1982), "the doctrine of primary jurisdiction is a reflection of the fact that when a court is confronted with a claim as to which it shares concurrent jurisdiction with an administrative agency, there may be sound reasons for the court to stay its hand until the agency has applied its expertise to the salient questions."

In such a case, "the judicial process is suspended pending referral of such issues to the administrative body." *AT&T Corp*., 1998 U.S. Dist. LEXIS 9175, at *4. A court may, in its discretion, stay the case and retain jurisdiction pending determination by an administrative agency. *Id*. at *19-20. Alternatively, the court may dismiss the case without prejudice. *Id*.

There is no fixed formula for whether a court should defer proceedings in a case under the doctrine of primary jurisdiction. *Id*. at *4. Rather, the court must evaluate on a case-by-case basis whether the policy considerations underlying the doctrine are present and whether applying the doctrine will serve those ends. More specifically, in determining whether to apply the doctrine of primary jurisdiction, courts are to consider whether: (1) the issue presented is within the conventional experience of judges or whether it involves technical or policy considerations

within the agency's particular field of expertise, (2) whether a substantial danger of inconsistent rulings exists if the matter is not referred, and (3) whether the administration of justice favors referral. *Id*. (*citing Nat'l Comms. Assn v. AT&T Corp*., 46 F.3d 220, 222-23 (2d Cir. 1995)).

For example, in *AT&T v. Ameritech*, *supra*, the plaintiff alleged that the defendant entered into an unlawful "teaming arrangement" with a third-party in violation of the Communications Act of 1934 (as amended). Applying the criteria set forth above, the district court determined that the doctrine of primary jurisdiction applied, and the court referred issues arising from the challenged "teaming arrangement" to the Federal Communications Commission ("FCC").

As to the first prong (whether the issue implicates agency policy considerations or expertise), the district court in *AT&T* determined that the comprehensive regulatory responsibility exercised by the FCC over the economically and technologically complex cable television industry militates in favor of allowing the agency to consider the matter in the first instance. As to the second prong (the danger of inconsistent rulings), the district court emphasized that referral to the FCC would promote a uniform, consistent, expert administration of the regulatory scheme entrusted to the FCC and would avoid contradictory rulings by the agency and the courts. As to the third prong (administration of justice), the district court acknowledged that referral to the agency would inevitably delay resolution of the case, but it would also allow the court to make a better-informed decision and reduce the likelihood of inconsistent rulings by the agency and the courts. Against this backdrop, the district court had no difficulty concluding that the benefits of referral far outweighed any resulting incremental delay. As a result, the district court entered an order staying the proceedings and retaining jurisdiction pending determination of the predicate issues by the FCC.

Federal courts around the country, including the U.S. Supreme Court and the Seventh Circuit, have invoked the primary jurisdiction doctrine to stay or dismiss proceedings implicating the regulatory authority of the FDA. *See, e.g., Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 93 S. Ct. 2488 (1973) (reversing appellate court and affirming district court order staying case based on FDA primary jurisdiction); *Tutoki v. Celebrezze*, 375 F.2d 105 (7th Cir. 1967) (affirming district court order dismissing complaint based on FDA primary jurisdiction).

In *Weinberger*, *supra*, the plaintiff drug marketers filed an action challenging the FDA Commissioner's order withdrawing approval of a new drug application. The plaintiffs contended that the drugs at issue were generally recognized as safe and effective and therefore were not "new drugs" for purposes of the application process. They also argued that their drugs should be deemed exempt under the grandfather clause of the relevant statutory provision.

On appeal, the U.S. Supreme Court rejected the plaintiffs' assertion, finding that it was "implicit in the FD&C Act's regulatory scheme that the FDA has jurisdiction to decide with administrative finality, subject to judicial review, the 'new drug' status and 'grandfather exemption' issues." *Id*. at 645. The Court emphasized that both issues were "peculiarly suited to initial determination by the FDA given its specialized competence and expertise." *Id*. The Court also held that it is not sufficient for the party opposing referral to argue that the safety or efficacy of the drug will be a subject of disputed expert testimony:

> Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without a chemical or medical background. The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.

Id. at 653-54. Where a threshold issue falls within the specialized experience or discretion of the agency created by Congress to regulate in that area, the agency should not be passed over.

Similarly, in *Tutoki*, *supra*, the Seventh Circuit affirmed the district court's order dismissing the plaintiffs' lawsuit based on the primary jurisdiction doctrine. In that case, a putative class of plaintiff cancer patients alleged that the defendant Secretary of the U.S. Department of Health Education and Welfare arbitrarily and unconstitutionally prevented the interstate shipment of the cancer drug Krebiozen (a drug that had not been approved by the FDA and for which no application was pending). In rejecting the plaintiffs' claims, the Seventh Circuit emphasized that "an essential element of proof by plaintiffs would be a showing that if the FDA had passed on Krebiozen according to statutory and constitutional standards, it would have been approved or exempted." The Court went on to state that "the relief sought by plaintiffs . . . presupposes a determination by the district court that Krebiozen should be approved for interstate shipment or exempted from the prohibition pursuant to the standards Congress enacted in the [FDC Act]."

Relying on long-standing precedent, the Seventh Circuit held in *Tutoki* that the determination at issue was within the primary jurisdiction of the FDA:

> In cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.

Id. (citing *Far East Conference*, 342 U.S. 570, 574-75 (1952)). Applying these factors, the Seventh Circuit noted that "the district court has neither the facilities nor the expertise to pass on Krebiozen in the first instance" and that "the possible conflict of a judicial determination of this question with a subsequent FDA decision on Krebiozen" bolstered its view that the primary jurisdiction doctrine should apply.

The same analysis that supported the application of the primary jurisdiction doctrine in *Weinberger* and *Tutoki* supports application of the primary jurisdiction doctrine to stay the proceedings in this case until the FDA resolves the underlying predicate issues.

1. Issue Involved Implicates Agency Policy Considerations and/or Expertise:

As noted above, each of plaintiff's claims is predicated on the dubious proposition that the trace levels of lead allegedly found by CSC are actually harmful, thereby triggering labeling or other disclosure obligations. As a result, one of the essential elements of proof by plaintiff in this case will be a showing that the mere 0.21 ppm of lead allegedly found in Dior® Addict Positive Red lipstick is unsafe and that LVMH therefore had an affirmative duty to disclose the presence of lead under the applicable FDA regulations or other relevant law. As the Seventh Circuit ruled in *Tutoki*, such issues squarely implicate FDA expertise and policy considerations.

First, the FDA has comprehensive authority with respect to the regulation of adulterated and misbranded cosmetics. The complex regulatory scheme includes, among other things, certification of color additives used in cosmetics, establishing maximum lead-content and other heavy metal levels for color additives, establishing packaging and labeling standards for cosmetics, and establishing PTTIL standards for lead and other heavy metals for adults and children based on specialized agency knowledge and expertise. Notably, the FDA also exercises its discretion to establish maximum lead-content levels for regulated products when it sees fit to

do so. For example, the FDA enacted the 0.1 ppm maximum lead content standard for candy to help bring the amount of lead ingested by children within acceptable limits (not, as plaintiff suggests, to reduce the amount of lead ingested by children to zero).

Second, determining whether the reported trace levels of lead are sufficiently safe necessarily involves complex chemical and scientific considerations that are beyond the conventional experience of the courts. If allowed to proceed, both parties will adduce "expert" testimony regarding the safety or danger of trace amounts of lead in lipstick. As noted in *Weinberger*, however, evaluating "conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without a chemical or medical background." Likewise, evaluating conflicting reports from experts in the field regarding the danger or safety of trace levels of lead in lipstick is not a matter well left to the courts, which have neither the facilities nor the expertise to engage in the requisite level of scientific inquiry.

In short, with its state-of-the-art laboratories, teams of scientists and other technical personnel, flexible process, and awareness of its own administrative priorities, the FDA is far better equipped than the courts to determine initially whether the complained-of lipsticks contain dangerous or otherwise actionable levels of lead from a technical, scientific, public policy, or other regulatory perspective.

2. Substantial Danger of Inconsistent Rulings:

In this case, there a substantial risk of inconsistent rulings between this Court and the FDA. In addition, because there are several copycat lawsuits pending in this District and other jurisdictions, there is also a risk of inconsistent rulings between and among the courts.[17] Action by the various courts involved in the pending cases, without FDA input, would potentially be detrimental to the fair and efficient administration of justice. Among other things, it could result

[17] *See*, *supra*, fn. 10.

in a patchwork of inconsistent rulings and regulations that would be inconsistent with federal uniformity and disruptive to interstate commerce. Staying this case (and all related cases) pending resolution of the predicate safety and labeling issues by the FDA would minimize this risk. In short, by giving the courts the benefit of the FDA's considered scrutiny of the relevant issues, the courts will be able to make decisions that not only are better informed, but comport with the FDA's regulatory priorities and factual findings.

3. Administration of Justice:

Even where a referral to an agency is likely to delay resolution of the case, courts have held that "the minimal delay occasioned by referral is less weighty than the need to provide the court with the benefit of the agency's views and to allow the agency to play the role envisioned by Congress." *AT&T*, 1998 U.S. Dist. LEXIS 9175, at *12. This is particularly true where, as here, the agency in question has already begun its investigation, at least in part at the request of interested members of Congress. There is every reason to take the FDA at its word that it is moving promptly to provide its perspective on the underlying issues.

In short, the nature of the issues, the risk of inconsistent rulings, and the very brief delay involved versus the advantage of having the FDA's administrative record and views before the Court, all weigh heavily in favor of the requested stay.

CONCLUSION

For all of these reasons, Defendant LVMH Perfumes and Cosmetics, Inc. asks this Court to grant its motion and stay all proceedings in this action (and any after-filed related lawsuits) until the FDA completes its ongoing evaluation of the predicate issues. LVMH also requests that this Court set this matter for further status in sixty (60) days.

Date: January 31, 2008

Respectfully submitted,

LVMH PERFUMES AND COSMETICS USA, INC.

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CERTIFICATE OF SERVICE

I, Robert E. Shapiro, an attorney, hereby certify that I caused a true and correct copy of the Defendant LVMH Perfumes and Cosmetics, Inc.'s foregoing **Memorandum of Law in Support of its Motion to Stay** to be served upon the following on this date, January 31, 2008, by ECF/PACER electronic notice and by U.S. Mail as indicated:

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